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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,891

09/30/2003

Vaclav O. Podany

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05/25/2006

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,891

Applicant(s)

PODANY ET AL.

Examiner

Michael Peffley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Applicant's amendments and comments, received April 13, 2006, have been fully considered by the examiner. The following is a complete response to the April 13, 2006 communication.

Election/Restrictions

The examiner maintains the election as presented in the previous Office actions is proper and is maintained.

Applicant again argues that claim 11 is generic to all Species. The examiner again disagrees. There is nothing shown in Figures 1-3 that supports a means to vary the distance of an ultrasonic transducer as set forth in claim 11. Moreover, there is nothing in the specification that suggests that the transducer from Figures 1-3 may be provided in the device of Figures 7A and/or 7B. The specification clearly acknowledges that Figures 7A and 7B are a separate embodiment. There is nothing in the specification that supports modification of Figures 1-3 such that the device would have means for varying the distance of the ultrasonic transducer. Even if there were such a suggestion, this would be deemed yet another embodiment. Further, claims 17-19 recite independent and distinct means for varying the distance of the ultrasonic transducers, which means are not represented in applicant's elected invention of Figures 7A and 7B.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the reflector (claim 6), and the ultrasonic transducer element in combination with the compliant member for

varying distance and further including electrodes must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Applicant asserts that Figures 2 and 8 disclose a reflector (i.e. window). A window is not deemed a reflector and is used to deliver, not reflect, energy. Paragraph [0044] specifically indicates that a reflector may be provided on the embodiment of Figure 7A, but fails to show such an element in the drawings. Again, the feature must be shown or canceled from the claim. No new matter should be entered.

Applicant also states that an ultrasonic transducer element in combination with a compliant member with electrodes is shown in at least Figures 7A, 7B and 8. The examiner disagrees. There is no depiction of an ultrasonic transducer in combination with the compliant member in these Figures. That the specification may allude to the use of alternative energy means is not a direct representation in the figures of such an arrangement.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification provides a very vague description for several of the embodiments of the invention without providing a sufficiently detailed description of these embodiments to allow one skilled in the art to make and/or use the invention. For example, applicant has elected the embodiment of Figures 7A and 7B. The description of this embodiment describes a compliant material having electrodes (1010a, 1010b) on the compliant material. Paragraphs [0043] and [0044] suggest that the electrodes may be connected to an energy source such as ultrasound, microwave, cryoablation, RF, etc, or that alternatively an ultrasonic vibratory element may be provided. However, these various energy sources required substantially different construction in order to

operate, and applicant's specification fails to show or describe how these various modalities are enabled. With particular reference to the claims that recite an ultrasound transducer, it is not shown nor is it described how the transducer would be attached to the compliant material to enable its use. Figures 1-4 show various embodiments that specifically include an ultrasonic transducer. However, these embodiments include a transducer head (12) for mounting the transducer and do not include the compliant material recited in the claims and depicted in Figures 5-8. There is simply no disclosure adequately describing a compliant applicator that includes an ultrasound transducer as set forth in the claims. The specification also fails to enable a device that includes an applicator having an ultrasound transducer and a compliant material and an electrode located on the surface of the compliant material as recited in claims 14-16.

Applicant contends that the disclosure in paragraphs [0043] and [0044] adequately provides support, and the examiner disagrees. The embodiments that specifically show and describe an ultrasonic transducer (i.e. Figures 1-3) make no mention of a compliant material as required in the instant claims and shown in the embodiment of Figures 7A and 7B. That the specification may suggest alternative energy modalities are contemplated is not an express disclosure of providing such an instrument. There is no suggestion in the specification that the ultrasonic transducer assembly from Figures 1-3 could be substituted into the embodiment of Figures 7A and 7B. It is not clear nor is it intuitive how the ultrasonic assembly of Figures 1-3 would be adhered to or otherwise used with the compliant material shown in Figures 7A and 7B. For instance, it is not clear where on the compliant member an ultrasonic transducer

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would be mounted, particularly give the bulky nature of a transducer member relative to the electrodes shown in the compliant member. The examiner maintains that significant structural changes would have to be made to account for the mounting of an ultrasonic transducer (e.g. as shown in figures 1-3) to the compliant material of Figures 7A and 7B, and such changes would not be intuitive or obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-6 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sliwa, Jr et al (2002/0042610).

Sliwa, Jr et al (Sliwa) discloses an ablation apparatus that includes a first rigid support member (402 – Figure 67), a first compliant material (460) coupled to the support member and including a passage for infusing a medium to the compliant member (see Para. 0211). Sliwa specifically states that the compliant member may be used to vary the distance of the transducer to the tissue (Para. 0211). The transducer includes an electrode (420) for energizing the piezoelectric element and conducting energy to tissue. The device includes a plurality of these supports (402) connected in a

side-by-side manner for creating circular lesions. The support members may articulate relative to each other (Figure 67).

Claims 1-3, 6-8 and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Maguire et al (6,547,788).

Maguire et al disclose a device that comprises a rigid or semi-rigid support member (i.e. catheter 102) with a first compliant material (balloon 108) coupled to the support member. Maguire et al disclose a variety of energy emitting members associated with the compliant member, including ultrasonic transducers within the balloon (Figures 10A-10O) and electrodes within or on or embedded in the balloon (column 21, lines 1-17). Figure 10L shows the use of a reflective material (1060) to control the direction of the propagated ultrasound energy. The balloon (i.e. compliant member) is provided with first and second passages (1007 -Figure 10d) for circulating a medium to inflate/cool the balloon. See also column 38, lines 10-15. Maguire et al also provide for first and second compliant members (Figure 5G), in which case the more proximal portion of the catheter (310) is deemed to be the first support member, and the portion of the catheter after element 120 is deemed to be the second support member, which support members are fixed relative to one another.

With regard to applicant's claim 11, the balloon of Maguire et al is also the "means for varying distance" as the inflation of the balloon will inherently control the distance the transducer is from tissue. As addressed above, Maguire et al disclose

passages for circulating a fluid through the compliant member (i.e. balloon), as well as providing electrodes on/in the balloon.

Response to Arguments

Applicant's arguments filed April 13, 2006 have been fully considered but they are not persuasive.

The response to applicant's arguments with respect to the election, drawings and 35 USC 112 issues have been presented in the appropriate sections above.

With regard to the prior art, applicant contends that the Sliwa reference does not teach each and every feature of the claims. The examiner disagrees. Applicant is correct in indicating that the examiner is relying on cells (402) as the support member. However, there is nothing in the instant application claims that would preclude the examiner from interpreting the adjacent cells as the support member. Clearly, the adjacent cells would inherently serve as support members. Sliwa et al does teach an electrode, which electrode is inherently necessary for driving the ultrasonic transducer. Applicant's claims do not specify what type of electrode is provided, or how it is used to deliver energy to tissue. Applicant also states on page 9 of the response that applicant's claims omit the vacuum ports that are required by the Sliwa device. This is a moot point since additional elements found in a prior art does not preclude the reference from meeting the claimed limitations, particularly in claims with an open-ended transitional phrase (i.e. "comprising").

Applicant is arguing the intended use of the device when addressing the Maguire et al reference. Claims 1 and 11 have been amended to recite that the device is used

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to deliver energy to an outer surface of tissue. Applicant contends that the Maguire device is disclosed as being used within blood vessels and therefore does not anticipate the amended claims. The examiner disagrees. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Clearly, the Maguire et al device is capable of being used to deliver energy to an outer surface of tissue, whether it be tissue accessible by a body lumen (e.g. the heart or the prostate) or simply skin tissue. That Maguire et al disclose the use of the device within the body to treat internal tissue does not limit the use of the device solely in that capacity. The Maguire et al device is clearly capable of being used to treat a variety of tissues and therefore inherently meets the intended use limitations now set forth in claims 1 and 11.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

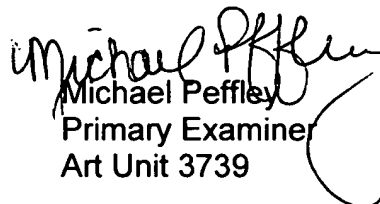
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

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May 19, 2006